DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 160-162, in the reply filed on 1/09/08 is acknowledged.

Claims 143-159 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/09/08.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 160-162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsen et al [US 6,013,447] in view of Taira et al [US 2004/0002077].

The invention is as clearly set forth in the claims.

Nilsen et al have taught a vectors and methods of their use in identifying affector RNA molecules (see Figure 1, for example). The vectors are taught to contain a "targeting gene" which encodes an affector RNA which is "an RNA molecule that is designed to alter, or preferably inhibit, the expression of an RNA of interest" where "preferred affector RNA molecules are ribozymes, external guide sequences, antisense RNA, and triple helix-forming RNA" (see columns 8-9, for example). These affector molecules are targeted to a fusion transcript that encodes a target nucleic acid molecule fused to a reporter molecule that can be directly or indirectly detected including a fluorescent polypeptide fusion (see columns 6-7, for example). Nilsen et al have taught a vector construct as recited for use in the instantly claimed method where the vector of Nilsen is used to identify affector RNA molecules. The difference between the prior art and the instant invention is the recitation of an RNA affector that induces RNA interference. RNA interference was not known at the time of Nilsens invention, but would be RNA affectors since they are RNA oligomers that inhibit a target nucleic acid

such as an mRNA. The prior art does indeed provide a description of such affectors expressed from a vector as required by the instant claims.

Taira et al have taught the expression of double stranded siRNA molecules from a vector where there is clearly a "promoter region" that provides for the expression of short double stranded RNAs (see Figures 1 and 2, for example).

Clearly one in the art would include the siRNA compounds of Taira et al in the vectors taught by Nilsen et al. Nilsen et al clearly describe their vectors for the general purpose of identifying RNA affector molecules of which siRNA would clearly be a member. Nilsen et al have taught that the vectors provide for an efficient method of detecting effective RNA affector molecules through the use of reporter target RNA fusions. The limitation of claim 162 where the polypeptide is lethal is considered an obvious variation for the following reasons. First, it is noted that the claim does not limit the polypeptide lethality to be due to the reporter aspect or the target RNA aspect of the fusion. Since the vector of Nilsen et al also comprises a second reporter it would have been a fine tool to detect the inhibition of lethal nucleic acids in a cell since the second reporter would provide evidence that the surviving cells contained the vector with the test affector RNA targeting a lethal target gene, for example. Furthermore, Nilsen et al teach that a reporter molecule can be directly or indirectly detectable. Clearly a reporter that is lethal would provide for a detection of cells inhibiting the fusion polypeptide and those that do not.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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